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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,632	04/02/1999	NATHANIEL T. BECKER	GC530-2	3949

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GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
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PALO ALTO, CA 94304

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/285,632	Applicant(s) BECKER ET AL.	
	Examiner Susan T. Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-27, 41, 42, 46-48 and 50-77 is/are pending in the application.
- 4a) Of the above claim(s) 57 and 59-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27, 41, 42, 46-48, 50-56, 58, 76 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time filed 11/07/03 and 12/11/03, Request for Continued Examination and Amendment filed 11/07/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/07/03 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-27, 46, 48, 54-56, and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Signorino US 5,480,479.

Signorino teaches a film-forming composition comprising water-soluble polymer including methylcellulose, modified starch, hydroxypropylmethyl cellulose, or mixtures of

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said polymers (column 4, lines 3-14). The composition further comprises pigment, dispersing agent, and plasticizer, including triethyl citrate, propylene glycol, and glycerin (column 3, lines 49-67; column 4, lines 44-60; and column (5, lines 25-29). The film-forming composition is suitable to coat capsule, tablet, and the like (column 3, lines 20-24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-27, 46, 48, 50, 52-56, 58 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Signorino.

Signorino is relied upon for the reason stated above. The reference is silent as to the teaching of the starch modification. However, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to, by routine experimentation selects the claimed modified starch, because Signorino teaches the use of modified starch, e.g. water-soluble modified starch in a water-soluble coating composition that provide a smooth, uniform coating for tablet, capsule, and the like (column 3, lines 20-24).

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Claims 41, 42, 47, 51, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Signorino, in view of Richardson et al. US 4,115,292.

Signorino is relied upon for the reasons stated above. The reference is silent as to the teaching of a granule-containing enzyme.

Richardson teaches a detergent article comprising enzyme core incorporated in a water-soluble compartment (coating), wherein the water-soluble compartment comprises water-soluble film-forming polymer, plasticizer, and surface active agent (see abstract, columns 2-3, column 6, lines 61-67, column 10, lines 26-68). Thus, it would have been obvious for one of ordinary skill in the art to use the water-soluble coating of Signorino to coat the enzyme article in view of the teaching of Richardson, because the references teach the use of similar water-soluble film-forming polymer to coat tablet, capsule, and the like.

Claims 41, 42, 47, 48, 50-53, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Signorino, in view of Oshlack et al. US 5,356,467.

Signorino is relied upon for the reasons stated above. The reference is silent as to the teaching of a granule core, wherein the core containing enzyme.

Oshlack teaches a pharmaceutical formulation in the form of tablets, beads, seeds, or granules that can be coated with a coating composition comprising water-soluble hydrophilic polymers (column 10, lines 45-06), modified starch (column 11, lines 12-41), and plasticizer (column 12, lines 29 through column 14, lines 1-40). The coating

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is useful for coating agricultural, food, household products, and pharmaceutical, e.g., tablet core, granule, microspheres, seeds, pellets, or beads (column 7, lines 28-40).

The examiner notes that Oshlack teaches the use of hydrophobic acrylic polymer in certain preferred embodiments. However, applicant has not provided any comparative data showing that the presence of the hydrophobic acrylic polymer would have a detrimental effect upon the desirability to obtain a useful coating composition. Hence, it would have been obvious for one of ordinary skill in the art to modify the water-soluble film forming composition of Signorino for the coating purpose in view of the teaching of Oshlack, because the references recognize the properties of modified starch and cellulose in coating composition useful for the same purpose desired by the applicant, e.g., coating composition for cleansing agent, therapeutic active agent, fertilizing agent, or disinfecting agent.

Response to Amendment/Arguments

Applicant's Amendment filed 11/17/03 indicated that claims 28-40 are being withdrawn. However, according to the record, claims 28-40 have been cancelled by the Amendment filed 04/02/01. Clarification is requested.

Applicant's arguments filed 11/17/03 have been fully considered but they are not persuasive.

Applicant argues that Oshlack does not teach a coating of 0.1% zein and applicant is under no duty to provide comparative results using 0.1% zein or another

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hydrophobic acrylic polymer. However, applicant has not shown that the coating composition of Oshlack is not water-soluble.

Applicant argues that the controlled release coating of Oshlack by definition, cannot rapidly dissolve in use because a coating could not provide "controlled release" of anything. In response to applicant's argument that the reference does not show certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., rapidly dissolve coating) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant claims and specification do not disclose, mention, or require the invention to be a rapid dissolve coating; nor applicant claims exclude the coating to be a "control coating".

Applicant argues that all of the present claims distinguish over Oshlack since all embodiments of Oshlack require a water insoluble polymer. Applicant further alleges that Oshlack's release rates are delayed release. Contrary to the applicant's argument, applicant's claims do not exclude the coating from "controlled release", "sustained release", or "delayed release". The time release being argued in page 3 of applicant's remarks is irrelevant with respect to the scope of the claims. The language "a coating" recites in the claims permits any type of coatings, including the control coating disclosed by Oshlack. Applicant has not limit the claims to a "rapid dissolve coating" or an "immediate release coating" per se. Thus, it is the position of the examiner that it would have been obvious for one of ordinary skill in this art to, by routine experimentation

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determine a suitable amount of water-soluble rate-controlling agent, erosion promoting agent, or pore-forming agent to obtain a desirable release/dissolution rate.

Applicant argues that the examiner continues to ignore the clear fact that all of Oshlack's embodiments have a hydrophobic, insoluble, acrylic polymer as the starting material for a "controlled release" coating. In contrast, applicant does not teach or describe a "controlled release" coating, but rather teach that soluble coating are desired, there was no reason for applicant to provide data in the specification comparing its coating to "controlled release" coatings. Contrary to the applicant's argument, the examiner acknowledged the present of hydrophobic acrylic polymer taught by Oshlack (Office Action dated 11/18/02). Nonetheless, as discussed above, applicant's claim language does not exclude the "controlled release" coating taught by Oshlack, therefore, it was suggested that applicant provides data showing detrimental effect in the use of hydrophobic acrylic polymer in an amount of 0.1%.

The Declaration under 37 CFR 1.132 filed 04/12/03 has been fully considered, but is insufficient to overcome the rejection of claims 22-27, 41, 42, 46-48, 50-56, 58, 76, and 77 based upon Oshlack et al. US 5,356,467 as set forth in the last Office action because it does not provide a side by side comparison of the claimed invention and those of Oshlack to support the statement "adding hydrophobic acrylic polymer would result in loss of the rapid release". There was no data or experiment in the Declaration showing the coating containing 0.1% hydrophobic acrylic polymer in combination of water-soluble rate-controlling agent, erosion promoting agent, or pore-former that would result in loss of the rapid release. In view of the foregoing, when all of the evidence is

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considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


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